Remarks

Claim Amendments

After entry of this amendment, claims 7, 9, 17-23 and 25-29 will be pending in the application.

Claim 7 has been amended herein. Claim 31 has been cancelled.

Support for the Amended Claims and Compliance with 35 U.S.C. § 132 and § 112 ¶ 1

The claims, as amended, were previously rejected by the Examiner as raising new matter and lacking written description for the phrase "but does not bind a polypeptide consisting of the amino acid sequence of SEQ ID NO:2." Applicants respectfully traverse.

The written description requirement of § 112 requires the application to convey with reasonable clarity to those skilled in the art that, as of the filing date, he or she was in possession of the invention. The claimed subject matter need not be described "*in haec verba*" in the original specification in order to satisfy the written description requirement. Rather, the test is whether a person of ordinary skill in the art would recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application. The same standards govern whether new matter has been added to the specification.

The present application discloses four human homologs of the FDF03 human receptor protein: FDF03-ΔTM, FDF03-S1, FDF03-M14 and FDF03-S2 (pages 5-11). The application acknowledges that FDF03 was previously described in International Application WO98/24906 by Adema et al., and specifically points to the structural and functional differences between FDF03 and the disclosed homologs (*id).* The application states that FDF03-S1 and FDF03-S2 receptor homologs could represent activation isoforms of the FDF03 receptor and states that these homologs could be advantageously used as population markers (page 11, lines 11-14.) The application discloses that the antibodies of the invention could be used as probes to distinguish tissue and cell type distribution, may be used to screen libraries for particular expression products, and could be used in diagnostic applications (page 21, line 5-19).

The application as originally filed included claims directed to: "[a]n isolated polyeptide comprising an amino acid sequence derived from SEQ ID NO:2 (FDF03), 4 (FDF03-ΔTM), 6 (FDF03-S1), 8 (FDF03-M14) or 10 (FDF03-S2)" (original claim 1), and to "[a] binding compound which specifically binds to the polypeptide of claim 1" (original claim 7). The pending claims relate to antibodies that specifically bind to an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO: 6 (FDF03-S1), but do not bind a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2 (FDF03).

Given the disclosure in the application (page 11, lines 11-14 and page 21, lines 5-19) and the originally filed claims, a person of skill in the art reading the application at the time it was filed would have understood that the inventors envisioned antibodies which ***specifically bound*** to each of the disclosed FDF03 receptor homologs, but did not bind to the FDF03 receptor or other homologs. This is evident from the fact that the specification taught about the use of the FDF03-S1/2 homologs as population markers, and the use of the antibodies in diagnostic applications. Clearly, antibodies that bind to the FDF03-S1 or FDF03-S2 receptor but cross react with the FDFO3 receptor would not be suitable for such applications. Further, based on the guidance provided in the specification and the state of the art at the time that the specification was filed, a person of skill in the art would have been able to make antibodies that bound to FDF03-S1 (SEQ ID NO:6) but did not bind to FDF03 (SEQ ID NO:2) using only routine experimentation. (*See, e.g*, Declaration under 37 C.F.R. § 1.132 of Joseph H. Phillips, submitted on May 21, 2007.) Accordingly, a person skilled in the art would have concluded that the Applicants were in possession of the currently claimed invention (antibodies which specifically bind to SEQ ID NO:6 but not to SEQ ID NO:2) at the time that the application was filed. Therefore, the pending claims do not add new matter and satisfy the written description requirement.

Rejections Under 35 U.S.C. § 112

Claims 20-23 and 26-29 were rejected under U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. According to the Examiner the specification does not enable the use a pharmaceutical composition comprising an antibody to SEQ ID NO:6 for the claimed intended uses. Applicants respectfully submit that this rejection has been rendered moot by the amendment to claim 7.

Claim 31 was rejected under 35 U.S.C. § 112, first paragraph, as lacking written description for the phrase "residues 195-205 of SEQ ID NO:6". Claim 31 has been canceled. Therefore, this rejection has been rendered moot.

Rejections Under 35 U.S.C. § 102

The Pending Claims Are Novel over Adema (WO 98/24906)

The claims are rejected under 35 U.S.C. § 102(b) over Adema. Applicants traverse.

Adema discloses and claims the protein FDF03, having the amino acid sequence of SEQ ID NO:2. The pending claims are directed to antibodies that bind to SEQ ID NO:6 but do not bind to SEQ ID NO:2. Thus the claims, as amended, are novel over Adema.

The Pending Claims Are Novel over Lal (US Publication 2005/0155089)

The claims are rejected under 35 U.S.C. § 102(e) as being anticipated by Lal. Applicants traverse.

Lal discloses the sequences of 184 proteins which contain a signal-peptide including a protein comprising the amino acid sequence of SEQ ID NO:6, but does not disclose any specific and substantial utility for any of these polypeptides. Therefore, as submitted in our reply to the previous office action, Lal does not enable a person of skill in the art to use the claimed invention and should not be prior art under 35 U.S.C. § 102(e).

The Examiner has rejected this argument citing to *In re Hafner* which states that "a disclosure lacking a teaching of how to use a freely disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim." *In re Hafner*, 410 F.2d 1403, 1410 (C.C.P.A. 1969).

Applicants traverse. The case cited by the Examiner, *In re Hafner*, can be distinguished from the present case because the reference considered in that case was prior art under § 102 (b), not § 102(e). While it is true that for anticipation, § 102(e) requires the invention to have been "described" similar to that required by §§

102(a) and 102(b), § 102(e) deals with "secret prior art" – *i.e.*, "an application for patent" – unlike §§102(a) and 102(b). Applicant sumbit that the proper standard is that articulated by the Supreme Court in *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390, #401 (1926), and the Court of Customs and Patent Appeals in *In re Wertheim and Mishkin*, 209 U.S.P.Q. 554 (C.C.P.A. 1981); namely, that a U.S. patent can anticipate under 35 U.S.C. § 102(e) as of a particular date only to the extent that there is a sufficient disclosure under 35 U.S.C. § 112, first paragraph, for the subject matter at issue (*i.e.*, the subject matter of the claims being rejected as being anticipated under § 102(e) by the patent).

The justification for giving a U.S. patent prior art status earlier than the date that the contents of the patent become public was first articulated in *Alexandar Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390, 401 (1926). In *Alexander Milburn*, the Court noted that "[i]t is not disputed that this [§ 102(e)] application *gave a complete and adequate description of the thing patented to Whitford,* but it did not claim it." *Id.* at 399 (emphasis added). The Supreme Court reasoned that a patent owner should not be penalized for the administrative delays associated with examining and granting patents. According to *Alexander Milburn,* if a patent application could issue *claiming the subject matter at* issue on the same date it was filed - but for PTO prosecution delays – it should have prior art effect as from the date of its filing. *Id.* at 401 ("Delays in the patent office ought not to cut down the effect of what has been done. The description [in the § 102(e) reference] shows that Whitford was not the first inventor.") The critical point was that a patent could have issued claiming the subject matter at issue.

In view of the *Alexander Milburn* Court's recognition in establishing § 102(e) prior art that the patent reference there involved provided a "complete and adequate description of the thing claimed [in the later filed patent]" to be "an anticipatory disclosure" under § 102(e), the disclosure of the reference must meet the requirement of 35 U.S.C. § 112, first paragraph for the invention at issue. That is, the specification must provide, *inter alia,* a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art...to make and use the same." 35 U.S.C. §112, first paragraph. "The disclosure of how to use must relate to a use of the kind considered by the Supreme Court in *Brenner v. Manson* [383 U.S. 519, 86 S.Ct. 1033, 148

U.S.P.Q. 689 (1996)] to be a sufficient utility." *In re Hafner,* 410 F.2d 1403, 1405, (C.C.P.A. 1969). To not require such compliance would extend the secret prior art doctrine beyond logic because the prior art disclosure could not have issued as a patent claim the day it was filed.

The decision in *In re Wertheim,* 541 F.2d 527, (C.C.P.A. 1981) confirmed the Supreme Court's requirement in *Alexandar Milburn* that to be given prior art effect as of the filing date of the U.S. application, the invention disclosed in the patent and being used as prior art must be a *complete and adequate description* of the later application's claims to constitute *prima facie* evidence that the applicant is not the first inventor of the invention in controversy.

For example, in *Wertheim,* the court addressed the specific question of the effective date of *a claimed invention* – for prior art purposes – to be given to a patent under §§ 102(e)/103, where the application on which the patent issued added new matter to the original application upon which it was based and wished to claim the benefit of that earlier application under § 120. The court held that the § 102(e) effective date of the patent was limited to that subject matter in the patent (*i.e.,* either in its priority document or in the patent specification itself) that could satisfy the requirements of § 112, first paragraph, relative to the claims being rejected. *Wertheim,* 541 F.2d at 537, (C.C.P.A. 1981). The court recognized that a patent-should be entitled to prior art effect-under § 102(e) *only as to subject mater that was disclosed in a manner that would be sufficient under § 112, first paragraph* because it was concerned that the secret prior art doctrine would otherwise be extended beyond logic. *Id.* ("We will extend the 'secret prior art' doctrin of *Milburn* and *Hazeltine* only as far as we are required to do so by logic of those cases.")

The decision in *Hafner, supra,* can not be used to contravene the Supreme Court's requirements in *Alexander Milburn, supra,* and the Court of Customs and Patent Appeals' decision in *Wertheim, supra. Hafner* involved a reference that qualified as prior art under § 102(b), not § 102(e). *See Hafner,* 410 F.2d at 1404. As noted above, § 102(b) concerns information that was in the public's hand more than one year before the date of the application for patent in the United States. 35 U.S.C. §§ 102(b) and 103(e). Thus, while *Hafner* may stand for the proposition that in order to qualify as anticipatory prior art under § 102(b) a reference need not disclose how to use the subject matter at issue sufficient to meet 35 U.S.C. § 112, first paragraph,

they do not answer the question at issue here of the appropriate effective filing date of a § 102(e) reference.

In order for a patent to have issued to Lal on the claimed subject matter of (an antibody or fragment which specifically binds to an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO:2) Lal had to disclose a specific substantial and credible utility for the polypeptide.

As previously submitted, Lal discloses 184 human signal peptide containing proteins (HSPP) and the only uses disclosed for these polypeptides is the general use of "diagnosing, treating, or preventing disorders associated with expression of HSPP" (see abstract and pages 138-140). Thus, the disclosed utility is not specific or substantial and would not meet the requirements of 35 U.S.C. § 112, first paragraph.[1] Thus, Lal would not have been able to obtain a patent claiming the subject matter of the claims pending in this application. Therefore, Lal is not a proper § 102(e) reference.

Rejections Under 35 U.S.C. § 103

The claims are also rejected as obvious over Lal in view of Markussen. Applicants traverse.

As discussed above, Lal is not a proper prior art reference under § 102(e). Thus, it cannot be used as a basis for an obviousness rejection.

Furthermore, since neither Lal or Markussen disclose a substantial and specific utility for a protein comprising of the amino acid sequence of SEQ ID NO:6. A person of skill in the art would not have been motivated to combine these references to arrive at the claimed invention.

In view of the arguments presented above, Applicants respectfully submit that the claims are novel and non-obvious over Lal.

---

[1] In fact the claims elected for prosecution in the Lal application (which do not relate to FDF03-S1) were rejected for lacking a specific or substantial utility.

Conclusion

Applicants respectfully submit that the instant application is in condition for allowance.

Respectfully submitted,

Schering-Plough Corporation
2000 Galloping Hill Road
K-6-1-1990
Kenilworth, New Jersey 07033-0530
Tel: (908) 298-2266
Fax: (908) 298-5388

Gloria Fuentes
Attorney for Applicants
Reg. No. 47,580